DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 13-718/S-020 & S-021

Bio-Technology General Corporation
Attention: Briti Kundu
Director, Regulatory Affairs
70 Wood Avenue South
Iselin, New Jersey 08830

Dear Ms. Kundu:

Please refer to your supplemental new drug applications, supplement - 020 and supplement - 021 dated October 24, 2001, received October 25, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Oxandrin (oxandrolone) Tablets.

We acknowledge receipt of your submissions to supplement – 020 dated January 30, April 25, June 22, and October 24, 2001. We also acknowledge receipt of your submissions to supplement – 021 dated June 12, September 19, and October 24, 2001. Your October 24, 2001, submissions completed the response to our action letters dated June 14 and October 1, 2001, for supplement – 020 and supplement – 021, respectively.

Supplement - 020 provides for the addition of DSM-Catalytica Pharmaceuticals as a alternate manufacturing site for the drug product.

Supplement - 021 provides for the addition of a new 10 mg strength tablet to be manufactured and tested at DSM-Catalytica Pharmaceuticals Inc. This supplemental new drug application also provides for the inclusion of Applied Analytical Industries (AAI) as an alternate testing laboratory.

We have received reports of satisfactory inspections of the manufacturing facilities and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert and immediate container label submitted to supplement - 021 on September 19, 2001).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 13-718/S-021." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the new 10mg formulation of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call William C. Koch, R.Ph., Regulatory Project Manager, at (301) 827-6412.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic
and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research